DRAFT NOT FOR IMPLEMENTATION

Guidance for Industry and FDA

Guidance for Infant/Child Apnea Monitor 510(k) Submissions

Draft Guidance – Not for Implementation

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Preface

Public Comment:

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket No. assigned to that notice, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

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Introduction

Background

FDA is proposing to remove apnea monitors from their current classification within the generic type of device known as the breathing (ventilatory) frequency monitor (§868.2375). The proposed rule would classify the apnea monitor as a group in class II (special controls), with an industry guidance document issued by FDA as the special control. The generic apnea monitor would include devices used to monitor apnea, i.e., the cessation of breathing, in all patient populations. The infant/child apnea monitor used on infants and children under three years of age will fall within the generic type of device proposed for classification as the apnea monitor. The draft guidance describes minimum performance characteristics, testing procedures and criteria, labeling, and, as appropriate, clinical testing recommendations for certain apnea monitors, i.e., infant/child apnea monitors. After considering comments on this draft guidance and further evaluating appropriate clinical study parameters, FDA intends to modify the guidance so that the final guidance document is applicable as the special control for the apnea monitor used on patients in various age groups, as well as infants and children. FDA invites comments on how FDA may revise this guidance to apply to age groups other than infants and children.

This guidance document describes a means by which infant/child apnea monitors may comply with the requirement of special controls for class II devices. Designation of this guidance document as a special control means that manufacturers attempting to establish that their device is substantially equivalent to a predicate infant/child apnea monitors device should demonstrate that the proposed device complies with either the specific recommendations of this guidance or some alternate control that provides equivalent assurances of safety and effectiveness.

This guidance document has been developed as a special control to support a change in classification from class III to class II. It identifies relevant material on clinical studies and labeling to include in a 510(k) premarket notification application. We intend it be used in conjunction with other identified special controls. All FDA requirements regarding premarket notification submissions are not repeated in this document. Please refer to the following list for other applicable standards. Except as otherwise indicated, copies of these publications may be

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1 This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

purchased from the American National Standards Institute, 11 West 42nd St., New York, NY 10036.

(1) International Electrotechnical Commission (IEC) International Standard "IEC 60601-1 (1988) Medical Electrical Equipment Part 1: General requirements for safety..." (as amended), Amendment No. 1 (1991), Amendment No. 2 (1995).

(2) International Standard "IEC 60601-1-2 (1993-04): Medical electrical equipment Part 1: General requirements for safety 2. Collateral Standard: Electromagnetic compatibility-Requirements and tests..." First edition.

(3) International Standard "IEC 60529 (1989): Classification of degrees of protection provided by enclosures."

(4) International Standard "IEC 61000-4-1 (1992) Electromagnetic Compatibility (EMC) Part 4: Testing and Measurement Techniques - Section 1: Overview of Immunity Tests..."

(5) International Standard "IEC 61000-4-2 (1995) Electromagnetic Compatibility (EMC) Part 4: Testing and Measurement... Section 2: Electrostatic Discharge Immunity Test"

(6) International Standard "IEC 61000-4-3 (1995) Electromagnetic Compatibility (EMC) Part 4: Testing and Measurement... Section 3: Radiated, Radio-Frequency, Electromagnetic Field Immunity Test"

(7) International Standard "IEC 61000-4-4 (1995) Electromagnetic Compatibility (EMC) Part 4: Testing and Measurement...Section 4: Electrical Fast Transient/Burst Immunity Test"

(8) International Standard "IEC 61000-4-5 (1995) Electromagnetic Compatibility (EMC) Part 4: Testing and Measurement... Section 5: Surge Immunity Test"

(9) International Standard "IEC 61000-4-6 (1996) Electromagnetic Compatibility (EMC) Part 4: Testing and Measurement... Section 6: Immunity to Conducted Disturbances, Induced by Radio- Frequency Fields"

(10) International Standard "IEC 61000-4-8 (1993) Electromagnetic Compatibility (EMC) Part 4: Testing and Measurement... Section 8: Power Frequency Magnetic Field Immunity Test " First Edition.

(11) International Standard "IEC 61000-4-11 (1994) Electromagnetic Compatibility (EMC) Part 4: Testing and Measuring... Section 11: Voltage Dips, Short Interruptions and Voltage Variations Immunity Tests..." First Edition.

(12) International Special Committee on Radio Interference (CISPR) International Standard

"CISPR 11 (1997): Limits and methods of measurement of electromagnetic disturbance characteristics of industrial, scientific, and medical (ISM) radio-frequency equipment."

(13) International Special Committee on Radio Interference (CISPR) International Standard "CISPR 16 (1999): Specification for radio disturbance and immunity measuring apparatus methods – Part 1: Radio disturbance and immunity measuring apparatus."

(14) American National Standards Institute (ANSI)/Institute of Electrical and Electronic Engineers (IEEE) Standard "ANSI/IEEE C95.3-1991: Measurement of Potentially Hazardous Electromagnetic Fields - RF and Microwave."

(15) International Standard "IEC 60068-2-32 (1975): Environmental testing - Part 2: Tests - Test Ed: Free fall..." (as amended), Amendment No. 1 (1982), Amendment No. 2 (1990).

(16) International Standard "IEC 60068-2-64 (1993-05): Environmental testing - Part 2: Test methods - Test Fh: broad band random (digital control) and guidance."

(17) ANSI/ Association for the Advancement of Medical Instrumentation (AAMI) Standard "ANSI/AAMI EC13-1992: Standard for cardiac monitors, heart-rate meters and alarms." (Copies of this publication may be purchased from the Association for the Advancement of Medical Instrumentation, 3300 Washington Boulevard, suite 1440, Arlington, VA 22201, Washington, DC.)

Patient Monitoring

Primary Monitoring Modality

FDA recommends that each monitor provide:

- apnea monitoring as the primary modality
- a timer to measure and warning indicators for apnea duration
- a sensor fault alarm

You should incorporate a means for detecting apnea in the monitor's primary monitoring modality. The operator's manual should specify the types of apnea that the primary monitoring modality will detect.

You should include a timer to measure apnea duration, and a system of visual and audible warning indicators designed to activate (alarm) when the measured apnea duration exceeds the apnea duration setting. FDA recommends that apnea duration settings of other than 20 seconds require the use of tools or special procedures to change those settings from 20 seconds. You should include a visual indication that the apnea duration setting has been changed from 20

seconds. The indicators should activate within 2 seconds after the apnea duration setting is exceeded.

You should provide a sensor fault alarm for determining when the signal level from the primary sensor is outside the range of values specified for proper operation by the monitor manufacturer. When this condition occurs, audible and visual warning indicators should activate within 5 seconds. A sensor whose only failure mode is loss of output does not need to address this recommendation if loss of output results in an alarm.

Secondary Monitoring Modality

We recommend that each monitor provide:

- detecting a physiological consequence as the secondary modality
- warning indicators at preset physiological limits
- a sensor fault alarm

You should incorporate a means for detecting a physiological consequence of apnea in the secondary monitoring modality. A monitor that includes heart rate monitoring should meet the requirements of the standard, ANSI/AAMI EC13-1992, for pediatric monitors.

You should include a system of visual and audible warning indicators designed to activate (alarm) when the measured physiological parameter goes above or falls below a selected preset limits. Include a control for presetting secondary modality alarm limits. The warning indicators should activate within 5 seconds after the measured parameter is outside the range of values specified by the preset limit.

You should include a sensor fault alarm for determining when the signal from the sensor for the physiological parameter is outside the range of values. When this condition occurs, audible and visual warning indicators should activate within 5 seconds. A sensor whose only failure mode is loss of output need not address this recommendation, because loss of output results in an alarm.

Visual Status Indicators (alarms)

You should provide two types of visual status indicators.

- Warning indicators that indicate the need for immediate attention to the patient
- Ready indicators that indicate proper operation of the monitor

You should use different colors to distinguish the two types of visual status indicators. FDA recommends following these color conventions.

- Red for warning indicators
- Green for ready indicators

FDA recommends that all visual status indicators be clearly legible at a distance of 1 meter, when viewed by an individual with visual acuity of 1 (corrected if necessary), under conditions having a range of illumination from 100 lux to 1,500 lux. You should locate visual status indicators so that they are not obscured from view when the monitor is orientated for viewing during use as specified by the manufacturer. You should not include any means for disabling visual status indicators during operation. Reset controls for visual status indicators should function such that neither continuous activation nor failure of the reset control will permanently disable the status indicators. Warning indicators should continue being activated until they are manually reset, even if the condition causing indicator activation resolves. Visual status indicators should conform to the labeling recommendations in this guidance.

Audible Status Indicators (alarms)

FDA recommends using two audibly distinct types of audible status indicators, one for warning and one for ready. Warning indicators, which indicate the need for immediate attention to the patient, should be audibly distinct from other types of audible indicators. Ready indicators, which if provided indicate proper operation of the monitor, should be audibly distinct from other types of audible indicators.

FDA recommends that you use different sound characteristics, e.g., pitch, sound level, and time duration, to distinguish between the types of audible status indicators. Warning indicators should sound intermittently at intervals not to exceed 1 second in duration. Sound level measured at a distance of 1 meter should be at least 75 decibels (A-weighted) for home monitors and 70 decibels (A-weighted) for hospital monitors. Ready indicators should have distinctly different sound characteristics than warning indicators.

You should not provide any means for permanently disabling audible status indicators during operation. Except in the case of the low battery warning indicators, activation of any manual means for temporarily silencing a warning-type audible status indicator should be accompanied by an automatic realarming of the audible indicator within 2 minutes. It should also be accompanied by a visual indication of silencing. The warning-type audible indicator may automatically reset if the condition causing it to go off resolves, but any visual status indicator that comes on when a warning-type audible indicator starts sounding should continue to stay on until manually reset. Audible status indicator reset controls should function such that neither continuous activation nor failure of the reset control will permanently disable the status indicators.

Remote Alarm

You should provide a remote alarm unit with monitors intended for home use. The remote alarm unit should alarm when a warning indicator at the site of the patient has been activated and when the unit is unable to detect the status indicator signals from the monitor. Using a remote alarm

unit should not disable the status indicators at the monitor.

The remote alarm unit should have a visual power ready indicator (pilot light) and an audible power interrupt warning indicator. If the monitor is battery operated, the remote alarm unit should have audible and visual low battery warning indicators (alarms) that activate at least 15 minutes, but no more than 2 hours, before the battery has insufficient charge remaining to supply power for operation of the remote alarm unit. These low battery warning indicators should remain activated until the battery is depleted. The low battery warning indicators should have a means for silencing the audible low battery warning indicator but not for inactivating the visual low battery warning indicator.

If the device is line power operated, you should provide battery backup that automatically activates within 5 seconds after the line power fails for any reason. The battery should have sufficient capacity, when fully charged, to supply power for normal operation for at least 8 hours.

Self-test

Include a self-test in the monitor, for confirmation by the operator, to operate or exercise all visual and audible status indicators each time the monitor is turned on.

Clinical Testing

You should conduct clinical testing demonstrating the device performance. Clinical studies must comply with the applicable sections of 21 CFR Parts 50, 56 and 812.

The clinical study should demonstrate the performance of the device over the entire intended patient population. The clinical performance of the device should be compared to at least one reference physiological parameter that provides information concerning the respiratory status of the subject sufficient to permit the identification of central apneas, obstructive apneas, mixed apneas, and non-apneas. The reference parameter should not be the same as that measured by the device. (Note that nasal thermistors and capnographs have been used in some studies.) Central apneas, obstructive apneas, mixed apneas, and non-apneas should be identified, and the identification criteria provided. The clinical performance of the device should also be compared to that of a legally marketed predicate device with similar indications for use.

The apnea duration timer setting should be 10 seconds.

There should be at least 3 independent investigations and at least 20 subjects per investigation (i.e., a minimum of 60 subjects), where the target population is limited to children less than 3 years of age. Additional subjects may be needed to support broader indications.

For each subject, we recommend that you use only the first six apneas of each type (central,obstructive, and mixed) in the percent detection calculations.

We recommend that the study have at least 100 events of the types of apnea for which the device is intended to detect; however, you should provide any data regarding other types of apnea detected during the study.

At least one experienced healthcare practitioner should perform independent observation. The health care practitioner should be masked from the apnea and secondary modality detections of the device and predicate. Apneas that are 8 seconds and longer should be detected, observed, and recorded. Apnea detections observed for non-apneas and for apneas lasting less than 8 seconds and, with the exception of true secondary modality alarms; all patient and equipment alarms should be classified as false positives (FP). Observations of apneas lasting from 8 to 12 seconds (inclusive) in duration should be classified as true positives (TP). Apnea detections observed more than 12 seconds from the beginning of apnea should be classified as false negatives (FN).

You should

- Provide a complete description of the testing procedures, protocols, and results.
- Identify the number and type of events for each subject.
- Provide sample tracings that include the recorded patient physiological waveforms, masked, independent observations, and the apnea detections of the device and the predicate device.
- Provide a statistical analysis of the clinical performance data and include a description of the analysis with formulas, identification of each parameter, etc.

The following data should be provided by patient, investigation, and pooled for the entire study:

- Sensitivity of detection for central, obstructive and mixed apnea (Sensitivity = TP/[TP + FN] x 100%).
- Positive predictive value (Positive predictive value = TP/[TP + FP] x 100%).
- False alarm rate (false alarms per hour)
- Percent of all alarms which were false alarms

You should include the results of the clinical performance evaluations in the Healthcare Practitioner Operation Manual. The results should include a summary of the clinical performance evaluation procedures and protocols, a summary of the scoring criteria used during the evaluation, a summary of the analyses used, and a summary of the test results.

Electrical Performance

Battery Power

To assure the necessary, adequate, continuous, and safe use of battery power, we recommend the following:

- All line-powered monitors intended for use in the home should have a battery power backup which should, unless the overcurrent protection has activated, automatically activate when the line power fails.
- The monitor should be fully operational within 5 seconds after the battery backup power has activated.
- The battery should have sufficient capacity, when fully charged, to supply power for normal operation for at least 8 hours.
- Monitors intended for use in the home should have audible and visual low battery warning indicators (alarms) that activate at least 15 minutes, but no more than 2 hours, before the battery has insufficient charge remaining to supply power for monitor operation and which remain activated until the battery is depleted.

- You shouldInclude a means for silencing the audible low battery warning indicator.
- Ventilate housings containing batteries from which gases can escape during charging or discharging to minimize the risk of accumulation and ignition.
- Battery compartments should be designed to prevent the risk of accidentally short-circuiting the battery.
- If a safety hazard or monitor malfunction could result from incorrect connection or replacement of a battery, the monitor should be designed to prevent incorrect polarity of connection.

Electrical Power Indicators

To monitor electrical power use, you should:

- Provide visual ready indicators to indicate that the monitor is energized.

- Locate such indicators conspicuously on the device and distinguish between battery power and line power sources when both sources are provided.

- In monitors incorporating a means for battery charging, provide a visual indication that the battery is charging.

Overcurrent Protection

FDA recommends that you provide overcurrent protection for all line-powered monitors. An audible warning indicator should activate when the overcurrent protection device is activated and the monitor cannot be operated. This audible warning indicator indicator (alarm) should be capable of sounding for at least 15 minutes.

You should not fit monitors with protective devices that may cause disconnection of the monitor from the power line by producing a short-circuit which results in operation of an overcurrent protection device.

Dielectric Strength

FDA recommends that you adequately insulate power source lines, patient contact circuits, and transducer circuits to assure protection of the patient and monitor from overvoltages. Refer also to International Standard, IEC 60601-1, Clause 20.

AC (alternating current) Power Grounding and Polarity

You should demonstrate that monitors intended for home use that operate or recharge batteries from the AC power line function properly when operating from an ungrounded power source. If monitor power line connectors are not polarized, the monitor should function properly with both possible polarities of power line connector insertion.

Leakage Current

See International Standard, IEC 60601-1 for Type BF equipment.

Electromagnetic Compatibility

Electromagnetic compatibility (EMC) is described in the International Standard IEC 60601-1-2 (1993) with the replacement and additional requirements contained Subclauses 6.8.201(a) (except for the reference to 36.201.1.3), (b) and (c). You should address electromagnetic compatibility in the premarket notification by describing and testing the performance characteristics under all applicable circumstances:

- operating from grounded and ungrounded ac power sources (i.e., with the third-wire ground connected and with it disconnected at the plug end of the power cord)
- when recharging batteries from a grounded and ungrounded ac power sources

You should test devices for electromagnetic emissions and immunity to electromagnetic interference with the third wire ground connected at the plug end of the power cord. If the device

is intended for home use, you should test it with the third wire ground connected and with it disconnected at the plug end of the power cord.

Electromagnetic Energy Emissions

The device should operate within its specification without emitting electromagnetic energy in excess of the levels specified below. The required emission limit should be that specified by the IEC standard referenced above, adjusted downward by the rms sum of all errors in the measurement of that quantity.

Electromagnetic Energy Emissions Test Methods

You should make emissions measurements as specified in the referenced IEC standard . The required emission limit should be that specified by the referenced IEC standard , adjusted downward by the rms sum of all errors in the measurement of that quantity.. Emission in excess of the adjusted limit should constitute failure of this test. You should conduct these tests using passive patient simulators, which in general are not capable of simulating normal patient signals.

Radiated and Conducted Electromagnetic Energy

You should provide in the premarket notification the performance characteristics of the device relative to the requirements of CISPR 11 when tested as recommended in this guidance document.

Radiated and Conducted Electromagnetic Energy Test Methods

FDA recommends that you test the device according to CISPR 11.

Magnetic Fields

You should demonstrate the performance characteristics of the device relative to RE101 (Army, 7-cm distance) of MIL-STD-461D from 30 Hz to 100 kHz when tested at the 7-cm distance according to RE101 of MIL-STD-462D.

Magnetic Fields Test Methods

You should test the device for radiated magnetic field emissions between 30 Hz and 100 kHz as

specified in RE101 of MIL-STD-462D, using the Army 7-cm limit. You should measure at the 7-cm distance only.

Immunity and Electromagnetic Interference

The device should operate within its specification during and after exposure to electromagnetic interference at the levels specified below. The immunity level should be the level stated, adjusted upward by the rms sum of all errors in the measurement of that quantity, with the exception of the lower steady-state ac voltage limit and the line-voltage sag level, which should be adjusted downward by the rms sum of the measurement errors. The device should not, as a result of the specified test condition: indicate an equipment alarm, exhibit temporary degradation or loss of function or performance which requires operator intervention or system reset, or exhibit loss or corruption of stored data.

You should determine the immunity of the device to electromagnetic interference as specified in the IEC standard, with the modifications listed below. The immunity level should be the level stated, adjusted upward by the rms sum of all errors in the measurement of that quantity, with the exception of the lower steady-state AC voltage limit and the line-voltage sag level, which should be adjusted downward by the rms sum of the measurement errors. Any of the following should constitute failure of this test: an equipment alarm, temporary degradation or loss of function or performance which requires operator intervention or system reset, or loss or corruption of stored data. You should use patient simulators to provide simulated normal stimulus to sensors during electromagnetic immunity testing.

Electrostatic Discharge

The device should operate within its specification within 5 seconds of air discharges of 2, 4, and 8 kV, both positive and negative, applied to insulating surfaces and contact discharges of 2, 4, and 6 kV, both positive and negative, applied to conductive surfaces, both positive and negative, to include any point on the device accessible to the operator or patient, without the use of a tool, when tested according to IEC 61000-4-2, as specified in section 4.2. The device should operate within its specification within 5 seconds of contact discharges applied to horizontal and vertical conducting planes in the vicinity of the device.

Electrostatic Discharge Test Methods

FDA recommends that you test the device with air discharges at 2, 4, and 8 kV, both positive and negative, applied to insulating surfaces and contact discharges at 2, 4, and 6 kV, both positive and negative, applied to conductive surfaces. Failure to resume normal operation (with no

operator intervention) within 5 seconds of a discharge should constitute failure of this test. All test failure conditions listed above apply. You should test the device according to IEC 61000-4-2, with the following conditions and modifications:

- You should test the device according to the test method described in IEC 61000-4-2 for table-top equipment
- The relative humidity should not exceed 50 percent during air discharges.
- Air discharges should be conducted at 2, 4, and 8 kV. Contact discharges should be conducted at 2, 4, and 6 kV. Discharges of both positive and negative polarity should be conducted at each voltage. At least 10 single discharges at each voltage and polarity should be applied to each test point
- In addition to air and contact discharges directly to the device, contact discharges should be made to the horizontal coupling plane under the device and to the vertical coupling plane positioned parallel to the faces of the device. At least 10 single discharges at each test voltage and polarity should be applied to each test point

Monitors that are internally powered IEC CLASS II or circuitry isolated from earth ground may be tested in a way that ensures that there is no appreciable charge retention between individual test discharges. The electrical potential of the monitor may be equalized with that of the ground plane, between individual test discharges, by temporarily attaching a ground strap incorporating two 470 kilowatt resistors connected in series. This potential equalization connected should be disconnected and moved at least 1 meter away from the monitor during the application of individual test discharges.

Radiated Electromagnetic Fields

The device should operate within its specification during and after exposure to electromagnetic fields at frequencies between 80MHz and 2.5GHz at field (strengths up to 3 V/m (when unmodulated), amplitude modulated 80 percent with a 2 Hz sine wave or 100 percent with a square wave. A modulation frequency that is within each significant signal-processing passband of the device should used. For devices not having a defined passband, you should use a modulation frequency of 0.5 Hz. You should specify the modulation frequency in the premarket notification.

Radiated Electromagnetic Fields Test Methods

Test conditions

You should test the device for immunity to radiated electromagnetic energy over the frequency range 80 MHz to 2.5 GHz at a field strength of 3 V/m. The RF carrier should be amplitude modulated 80 percent by a sine wave or 100 percent with a square wave. You should use a modulation frequency that is within each significant signal-processing passband of the device should be used. For devices not having a defined passband, you should use a modulation frequency of 0.5 Hz. You should specify the modulation frequency in the 510(k) premarket application.

If a continuous sweep of the test frequency is used, the sweep rate should not exceed 0.1 MHz/second. If the sweep is incremental, the step size should not exceed 1 MHz and the dwell time at each frequency should be 10 seconds.

Devices which can operate from both line and battery power should be tested both with the ac power connection (e.g., power cord, battery charger) attached and detached from the device.

Patient simulators used during the test should be either simple passive devices, isolated from earth ground using fiber optics, or battery operated and shielded.

Connections not normally used during device operation that are made to the device to assess performance during the test should be isolated using fiber optics.

The radiated electric field should be linearly polarized. You should perform the test should be performed with both horizontal and vertical polarization.

A planar area of uniform field should be established, that contains the front surface of all components of the device under test, including cables. The boundaries of the area of uniform field should include the maximum planar area occupied in any orientation of the parts of the device. The E-field should be measured at multiple points within the area of uniform field, with all accessories and physical components of the device removed from the field.

Within the area of uniform field, the uniformity of the component of the electric field that is aligned with the intended E-field polarization should be -0, +6 dB, measured with no amplitude modulation present on the exposure field. At a minimum, point measurements should be performed at every incremental frequency in the 26 to 1000 MHz frequency range. E-field measurements should be made at uniformly spaced points throughout the entire surface of the area of uniform field for both horizontal and vertical polarization. The spacing between these points in both the vertical and horizontal directions should be 0.5 m or less. At each point, the component of the E-field that is aligned with the intended

polarization should not differ from the total E-field at that point by more than 3 dB.

For a given facility, if placement of absorber, antennas, and area of uniform field are carefully reproduced, it should be necessary to map the area of uniform field only occasionally, e.g. once per year. Prior to a series of tests, the area of uniform field should be checked along a vertical line near the center, with measurements made at uniformly spaced points having a spacing of 0.5 m or less.

RF electric field instruments and measurement procedures should meet the requirements of ANSI/IEEE C95.3 - 1991. The instruments should not perturb the E-fields being measured by more than 2 dB and should measure local E-field strength with an error of less than ±3 dB over the frequency range of use. The field-sensing elements of the instrument should fit within a spherical volume with a diameter of 15 cm. The instrument should be capable of measuring the magnitude of each of the three orthogonal components of the electric field. In addition, the instrument should be capable of determining the total electric field strength (the square root of the sum of the squares of the three E-field vector components). The above measurements should be measured accurately (±1 dB) regardless of the direction of the radiated electric field (i.e., the field measuring instrument should be isotropic).

When practical, you should repeat the test with each of the six faces of the device facing the antenna. To the extent possible, all cables should be horizontal over the majority of their length throughout the test.

You should use one or more of the following exposure methods:

(1)an open-area test site, with the signal and power leads fully extended horizontally;
(2) an anechoic chamber;
(3) a parallel-plate line;
(4) a screen room;
(5) a semi-anechoic chamber; or
(6) a TEM cell.

In order to cover the entire frequency range, you may use combinations of several exposure methods over the portions of the range for which they are most appropriate. Where the methods yield different results, the open-site test should take precedence from 26 to 200 MHz and the anechoic chamber test should take precedence from 200 MHz to 1 GHz.

Test setup

When practical, you should elevate all device components and cables at least 0.8 m above any conducting ground plane by low dielectric constant (<2.5), nonconducting RF-transparent material. When this is not possible, you should mount device components on a

bulk non-conducting support at least 0.1 m high. All device components should be at least 0.8 m away from any RF-reflecting objects (e.g., walls of the exposure facility). The distance may need to be increased at certain frequencies to achieve field uniformity.

For exposure methods in which the device cables cannot be extended fully, if the length of any conducting cable is 1 m or less, it should be arranged horizontally in the planar area of uniform field. If the length of any conducting cable is greater than 1 m in length, up to the first three meters should be bundled in a serpentine configuration in the planar area of uniform. Conductive leads should be configured on a clean, dry, plastic foam (e.g., Styrofoam®) sheet with the dimensions and construction. Support pegs should be made of dielectric (e.g., Teflon®) rods (one quarter inch in diameter). Cables in excess of 3 m should be bundled low-inductively and placed on the non-conducting support.

RF/EMI filters should be used at the device's ac power plug.

You should arrange all cables so that they are horizontal over the majority of their length throughout the test. You should arrange device cables 1 meter or less in length s horizontally in the planar area of uniform field. For cables greater than 1 meter and less than or equal to 3 meters in length, the cable should be bundled in a serpentine configuration in the planar area of uniform field. For device cables grater than 3 meters in length, the first 3 meters should be bundled in a serpentine configuration in the planar area of uniform field and the remainder should be bundled low-inductively an placed on the non-conductive support.

Patient simulators used during the test should be either simple passive devices, isolated from ground using fiber optic links, or battery operated and shielded. If the frequency step dwell method is used, the frequency step size should not exceed 1 percent of the fundamental and the dwell time should not be sufficient to allow the device to respond to the test. The dwell time should be based on the modality with the slowest response time and should be at least 3 seconds.

For modalities that average data over time, the minimum dwell time should be either 1.2 times the averaging period or 3 seconds, which ever is greater. If the averaging period is adjustable the averaging period used to determine dwell time should be the monitor's default averaging period, the period. If there is no default averaging period, the period used should be that which is expected to be used most often in clinical applications of the device.

If the continuous frequency sweep method is used, the rate of sweep should not exceed (4.5/X) x 10000 decades per second. Connections not normally used during the operation on the device that are made to the device to access performance during the test should be isolated using fiber optic links.

AC Voltage Fluctuations, Transients, and Surges

The following items apply to all devices that recharge batteries from or operate from the ac power line:

Steady-state voltage

The device should operate within its specification, without changing a voltage selection switch, when powered from line voltages between 95 and 132 volts rms. The battery power back-up, if featured, should automatically activate when the line voltage falls below the minimum level necessary for line-powered device operation, which should be no greater than 95 volts rms, and line-powered operation should automatically resume when the line voltage returns to the 95 to 132 volt range.

For monitors that recharge batteries from ac power lines and monitors that operate directly from an ac power lines, demonstrate the performance characteristics during and after power line dips to:

- less than 1 % of nominal voltage for 0.5 cycle
- 40 % of nominal line voltage for 5 cycles
- 70% of nominal line voltage for 25 cycles of the power frequency

when tested according to the International Standard IEC 61000-4-11.

For monitors that recharge batteries from an ac power line and monitors that operate directly from an ac power line demonstrate the performance characteristics during and after power line dips to less than 1 % of nominal line voltage for 15 seconds according to the standard IEC 61000-4-11. Test voltages should be step changes and start at a zero crossing.

Dropout

The device should operate within its specification during and after line voltage dropouts for durations of 10 milliseconds and less.

Slow sags and surges

The device should operate within its specification during and after line voltage surges to 150 V rms and sags to 90 V rms for durations of 500 ms and less.

Fast transient bursts

The device should operate within its specification during and after bursts of transients of

0.5, 1, and 2 kV, positive and negative, applied to AC power leads and transients of 0.25, 0.5, and 1 kV, both positive and negative coupled by way of a capacitive clamp to signal and interconnecting leads, that are specified to be 3 meters or more in length when tested according to IEC 61000-4-4, with the exception that the burst repetition frequency should not exceed 30 per minute.

The pulse repetition rate should be 5 kilohertz. You should not test patient cables directly, but you should attach them to the monitor during the testing of all other cables power lines. Application of test to power lines should only be made simultaneously with respect to the ground reference plane.

FDA recommends that you demonstrate the performance characteristics of the monitor during and after application of surges of 0.5, 1, and 2 kilovolts, both positive and negative, between ac power line(s) and ground, and application of 0.5 and 1 kilovolt, both positive and negative, between ac power line(s) (line-to-line), when tested according to IEC 61000-4-5. All other monitor cables should not be tested directly. You should describe the response of the monitor to each individual surge.

While only power lines are tested, you should attach all monitor cables during the test. Five surges at each voltage level and polarity should be applied to each power line at each of the following: positive and negative zero crossing and positive and negative peak of the AC voltage waveform.

While only power lines are being tested, you should attach all device cables during the test.

You should apply five surges at each voltage level and polarity to each power line at each of the following:

- the positive and negative zero crossing
- the positive and negative peak of the ac voltage wave worm

AC Voltage Fluctuations, Transients, and Surges Test Methods

You should perform the tests described below on all devices intended to recharge batteries or operate from the ac power line.

Steady-state voltage

You should

- Raise the line voltage to 132 volts rms and allow the device to stabilize.
- Test device operation according to sections (k) and (l).

- Repeat for a voltage of 95 volts rms.

For devices with battery backup, you should

- Simulate normal patient signals while reducing the line voltage to zero.
- Record the voltage at which the device switches to battery power. In addition to the failure criteria listed above, failure of the device to automatically switch to battery power, or switching to battery power before the line voltage reaches 95 volts rms should constitute failure of this test.
- Continue to test device operation while raising the line voltage to 120 volts rms. In addition to the failure criteria listed above, failure of the device to automatically switch to line power when the line voltage exceeds 95 volts rms should constitute failure of this test.

Dropout

You should operate the device at 95 volts rms, lower the line voltage to 0 volts for 10 milliseconds, and then restore it to 95 volts rms, doing so 10 times at a rate not to exceed 30 per minute.

Slow sags and surges

You should

- Operate the device at 120 volts rms.
- Raise the line voltage to 150 volts rms for 500 ms.
- Repeat at 10-second intervals for a total of 10 times.
- Again operate the device at 120 volts rms.
- Lower the line voltage to 90 volts rms for 500 ms.
- Repeat at 10-second intervals for a total of 10 times.

Fast transient bursts

You should

- Test ac power leads and signal leads according to IEC 61000-4-4 for type test of tabletop equipment, with the exception that the burst repetition frequency should not exceed 30 per minute.
- Test supply leads at 0.5, 1, and 2 kV, and signal leads at 0.25, 0.5, and 1 kV.

Fast surges

Test generator

The values of elements R_{s1}, R_{s2}, R_m, L_r, and C_c are such that the generator delivers at a single output a combination voltage/current wave characterized by a 1.2/50 μs voltage surge when measured across a high-resistance load (more than 100 ohms) and a 8/20 μs current surge when measured into a short circuit, i.e. the generator has an effective output impedance of 2 ohms.

The generator should be capable of producing an open circuit output voltage of up to 2 kV, both positive and negative polarity, with wave. The generator should be capable of delivering short circuit output current of at least 1 kA.

The generator should be triggerable so that the phase angle of the discharge can be set at 0, 90, 180, and 270 degrees with respect to the AC line voltage.

Test setup

You should use capacitive coupling to apply the combination wave to the AC power leads of the device under test.

You should use a decoupling network to isolate the device under test from the AC power network. Residual test pulse voltage on unsurged leads should not exceed 15 percent of the maximum applied test voltage when the device is disconnected. Residual test pulse voltage on the inputs of the decoupling network when the device and the power supply network are disconnected should not exceed 10 percent of the applied test voltage or twice the peak value of the power line voltage, whichever is greater.

Surges should be applied at the point where the device would normally be connected to AC line power.

For the line-to-line test, you should use an 18 uF coupling capacitor.

For the line-to-ground tests, a 10-ohm resistor should be used in series with the test generator and a 9 uF coupling capacitor should be used.

Test procedure

You should perform the line-to-line test using 1-kV surges of both positive and negative polarity applied using a generator source impedance of 2 ohms and coupling capacitance of 18 uF with the generator output floating.

You shoul perform the line-to-ground test using 2-kV surges of both positive and negative polarity applied using a generator source impedance of 12 ohms and coupling capacitance of 9 uF with the generator output grounded. You should repeat the test with surges applied successively between each line and ground.

You should apply Surges at each amplitude and polarity at phase angles of 0, 90, 180, and 270 degrees with respect to the ac line.

You should repeat each test 10 times at a rate of 1 surge per minute.

Conducted electromagnetic energy

The device should operate within its specification during and after exposure of each interconnecting cable, including power cables, to conducted electromagnetic energy at frequencies between 10 kHz and 100 MHz at the levels specified in CS114, Curve #3, of MIL-STD-461D, when tested according to CS114 of MIL-STD-462D. A modulation frequency that is within each significant signal-processing passband of the device should be used. For devices not having a defined passband, a modulation frequency of 0.5 Hz should be used. You should specify the modulation frequency in the 510(k) premarket notification.

You should test the monitor during and after exposure to conducted electromagnetic energy at 3 volts root-mean-square (measured before modulation is applied), modulated 80 percent with a 2 Hz sine wave over the frequency range beginning at the start frequency specified below and extending to 80 mHz when tested according to IEC 61000-4-6.

Conducted Electromagnetic Energy Test Methods

You should test the device for immunity to conducted electromagnetic energy on each power and signal lead at frequencies between 10 kHz and 100 MHZ at the levels specified in curve #3 of CS114 of MIL-STD-461D, using the test methods specified in CS114 of MIL-STD-462D, with the modifications and additions listed below.

- If continuous sweep of the test frequency is used, the sweep rate should not exceed 1 x 10^{-3} decades/second. If the sweep is incremental, the step size should not exceed 1 percent of decade, and the minimum dwell time is 10 seconds per step.

- A modulation frequency that is within each significant signal-processing passband of the device should be used. For devices not having a defined passband, a modulation

frequency of 0.5 Hz should be used.

- The leads under test should be elevated 5 cm above the ground plane.

- For power cables, the interference signal should be injected at a distance of 5 cm from the point at which AC line power enters the device. For battery chargers which plug directly into AC outlets, a 10 cm length of wire should be added between the LISN and the charger, and the test signal should be injected 5 cm from the charger. The low-voltage output cable of the charger should be elevated 5 cm above the ground plane.

Test conditions as described in subclause 36.202.5:

- You should use sine wave amplitude modulation at 80 percent depth and a frequency of 2 hertz.

- For power input lines and the equipotential ground connection, if provided, the start frequency should be 150 kilohertz.

- For every cable that can be connected to the monitor, other than power lines, you should determine the start frequency from the guidance given in Annex B, Figure B.1 of the International Standard IEC 61000-4-6, based upon the longest allowed cable length specified by the manufacturer. If the longest cable length is not specified, the start frequency should be 150 kilohertz.

- You should test Equipotential ground connections using an M1 coupling/decoupling network (CDN) as specified in Annex D, Figure D.2 of the International Standard IEC 61000-4-6.

- You should test patient cables using a current clamp. The patient end of the coupled cables that provide a conductive connection to the patient should be terminated so that the impedance between the monitor and the ground reference plane is between 105 and 190 ohms over the frequency range 150 kilohertz and 80 mHz. No intentional decoupling device should be used between the injection point and the patient coupling point. An artificial hand is specified in CISPR 14 should be applied to the patient end of the patient coupled cables. If required for proper operation of the monitor, an insulating material with a thickness of 5 millimeters or less may be applied between the metal foil of the artificial hand and the patient coupling point.

- If the frequency step and dwell method is used, the frequency step size should not exceed 1 percent of the fundamental and the minimum dwell time should be sufficient to allow the monitor to respond to the test signal. The dwell time should

be based on the modality with the slowest response time and should be at least 3 seconds. For modalities that average data overtime, the dwell time should be either 1.2 times the averaging period or 3 seconds, whichever is greater. If the averaging period is adjustable, the averaging period used to determine dwell time should be the monitor's default averaging period. If there is no default averaging period, the period used should be that which is expected to be used most often in clinical applications of the monitor.

- If the continuous frequency sweep method is used, the rate of the sweep should not exceed (4.5/X)x 10000 decades per second, where X is the dwell time in seconds, determined as specified in the section above.

- You should perform calibration of current injection clamps in a 150 ohm system

Magnetic Fields

You should use a modulation frequency that is within each significant signal-processing passband of the device. For devices not having a defined passband, you should use a modulation frequency of 0.5 Hz. You should specify the modulation frequency in the premarket notification.

You should demonstrate the performance characteristics of the monitor during and after exposure to 60 Hz continuous wave magnetic fields at 3 amperes per meter when tested according to the International Standard IEC 61000-4-8, with the exception that a maximum display jitter of 0.6 millimeters is allowed for cathode ray tube displays.

Monitors that recharge batteries or operate from an ac power line should be powered at a line frequency of 60 Hz during the test.

Magnetic Fields Test Methods

You should demonstrate the performance characteristics of the monitor during and after exposure to 60 Hz continuous wave magnetic fields at 3 amperes per meter when tested according to IEC 61000-4-8, with the exception that a maximum display jitter of 0.6 millimeters is allowed for cathode ray tube displays.

Quasi-static Electric Fields

You should demonstrate that the device operates within its specification during and after exposure to a sinusoidally varying electric field at 0.5 Hz with peak field strengths up to 2000 volts per meter. Note: This test simulates the movement of electrostatically charged fabrics and

objects that could come into close proximity to the device.

Quasi-static Electric Fields Test Methods

Test setup

You should test the device between parallel horizontal planes. They should be metallic sheets (copper or aluminum) of 0.25 mm minimum thickness which extend at least 0.1 m beyond the device. The horizontal planes should be separated by insulating material, with a separation at least three times the height of the device in the position of normal use.

The device should be supported by insulating material so that it is positioned entirely between 1/3 and 2/3 the distance between the horizontal planes.

Cables and tubing should be supported by insulating material at a height above the bottom horizontal plane of 1/3 the distance between the planes and should exit the test apparatus and continue at this height for at least 0.1 meter beyond the horizontal planes.

The output of a signal generator capable of producing a sinusoidally varying voltage at a frequency of 0.5 Hz with amplitude sufficient to produce peak electric field strengths up to 2000 V/m between the horizontal planes should be connected to the horizontal planes.

Note: $E_p = V_p/D$, where E_p is the peak field strength in V/m, V_p is the peak of the signal generator output voltage waveform, and D is the distance between the horizontal planes in meters.

Test procedure

You should adjust the signal generator peak output voltage such that the device is exposed to a sinusoidally varying electric field at 0.5 Hz with peak field strength of 500 V/m. Gradually increase the peak field strength to 2000 V/m.

Voltage Dips

Voltage dips are defined as short interruptions and voltage variations on power supply input lines.

Voltage Dips Test Methods

For devices that recharge batteries from the ac power line and devices that operate from the ac

power line, you should demonstrate the performance characteristics during and after power line dips to less that 1 percent of nominal line voltage for 0.5 cycle, to 40 percent of nominal line voltage for 5 cycles, and to 70 percent of nominal line voltage for 25 cycles of the power frequency, when tested according to the International Standard IEC 61000-4-11.

For monitors that recharge batteries from an ac power line and devices that operate directly from an ac power line, you should demonstrate the performance characteristics within 5 seconds after a power line dip to less than 1 percent of nominal line voltage for 15 seconds, when tested according to standard IEC 61000-4-1.

Test voltages changes should be step changes and start at a zero crossing.

For devices that recharge batteries from the ac power line and devices that operate from the ac power line demonstrate performance characteristics, without changing a voltage selection switch when powered from line voltage between 95 and 132 volts root-mean square.

Mechanical and Environmental Performance

Controls Protection

You should protect the controls of monitors intended for home use from inadvertent or unauthorized changes or adjustment. You should show how these means of protection are designed to prevent their defeat.

Connector Protective Incompatibility

You should

- Design monitor connectors, including those on wires and tubing, such that insertion into a receptacle other than one for which they are intended or into a receptacle using an improper orientation is not possible.
- Include a mechanism in electrical connectors of the monitor to prevent connection of the patient to a power source that may cause a current flow in excess of that specified in in this guidance.
- Ensure that electrode lead wires and patient cables comply with all applicable sections of 21 Code of Federal Regulations (CFR), Part 898 Performance Standard for Electrode Lead Wires and Patient Cables.

Mechanical Safety

You should

- Ensure that there are no exposed sharp edges in the monitor design and that the monitor will be mechanically stable in all intended positions of use.
- Provide protection to the operator and patient from moving parts.

Mechanical Shock and Vibration Resistance

You should test the monitor to the following severity levels as specified in the following procedures. After each of these tests, you should also visually inspect the device. Any evidence of damage or inability to perform within specification should constitute failure of the test.

IEC 60068-2-32 Shock Test (Free Fall)

- Height: 0:5m
- Duration at attitude: 2 falls on each face

IEC 60068-2-64 Broad Band Random Vibration Test

- Frequency range 10 to 150 Hz,
- Acceleration spectral density: 1(meter per second squared) squared per hertz (g^2/Hz) from 10 to 12 Hz, decreasing at a rate of 3 decibels per octave from 12 to 150 Hz.
- Duration: 30 minutes on each orthogonal axis

Fluid Spill Resistance

You should test the device as specified in Clause 44.6 of IEC 60601-1 according to the test method in IEC 60529 for drip-proof equipment. Following each of these tests, you should visually inspect the device . Any evidence of damage or inability to perform within specification should constitute failure of the test.

Temperature and Humidity

You should test the device as specified in Method Numbers 501.3, 502.3, and 507.3 of MIL-STD-810E. Failure of the device to perform within its specification should constitute failure of these tests.

The device should operate within its specification when operating in the environmental temperature range of 5°C to 40°C, and in the environmental humidity range of 15 percent to 95 percent, noncondensing.

The device should not be damaged and should remain operational within its specification after storage in the environmental temperature range of minus 40°C to 70°C and at relative humidity up to 95 percent, non-condensing.

Surface temperature

The temperature of all surfaces of the monitor with which an operator might come into contact

during operation should not exceed 50°C in an ambient of 35°C. The temperature of all surfaces with which the patient might come into contact should not exceed 41°C in an ambient of 35°C. Electrochemical transcutaneous sensors are permitted with maximum temperatures up to 44°C for less than 4 hours (at the same site) if adequate patient protection procedures are clearly described in the labeling.

You should

- Operate the device in an ambient temperature of 35°C.
- Measure the temperature of the device surfaces, which are not intended to contact the patient. The presence of any temperature greater than 50°C should constitute failure of this test.
- Measure the temperature of device surfaces, which are likely to contact the patient in normal use. Any temperature above 41°C should constitute failure of this test.

Toxic Materials

You should determine by inspection that listed and any other known toxic materials used in the device are packaged in a manner that prevents patient and operator contact. No toxic material from a device should come in contact with patient or operator during normal use.

Strangulation

You should make provision- in routing, retention devices, or other means to minimize the risk of strangulation of the patient by wires or tubing. You may also accomplish this by providing instructions for routing of patient wires and tubing in the device labeling.

Device Labeling

General

In addition to the labeling requirements for prescription devices in 21 CFR Part 801, FDA recommends that the labeling of infant/child apnea monitors:

- prominently states the intended uses and limitations of the device
- provides instructions
- describes potential device malfunctions
- contains adequate operation, maintenance, and service information

Home Use Operator Information

FDA recommends that infant/child apnea monitors intended for home use include an operator instruction manual for laypersons. The manual for laypersons should be at approximately a

seventh grade reading level, and include numerous supporting illustrations. (See also other CDRH guidances, Write It Right and Human Factors Principles for Medical Device Labeling.) In the premarket notification, you should include data demonstrating the effectiveness of instructions in the manual.

FDA recommends that the manual contain:

- Intended Use
- Precautions and Hazards
- Monitor information
- Operating information
- Operator maintenance instructions
- Patient information
- Operating environment information
- Service information

Intended Use

You should provide a statement of the intended uses (i.e., purpose) of the monitor and an explanation of how the monitor accomplishes that purpose, including: a discussion of the types of apnea that the device monitors, the parameters monitored by the secondary monitoring modality, and the type of sensors used.

Precautions and Hazards

- precautions to minimize the risk of strangulation
- precautions to minimize hazards due to exposure to toxic materials from the monitor occasioned by abnormal conditions
- discussion of other hazards and risks associated with the monitor

Monitor Information

You should explain the function and meaning of each alarm and indicator provided with the monitor. Include a statement that the monitor may not be able to detect all episodes of apnea.

Operating Information

Operating information in the manual should include: general information, instructions for monitor setup, check-out, and operation.

In the general operating information you should:

- list additional reference materials available to the layperson about apnea

monitoring and where such materials can be obtained
- state when it may be appropriate to contact the prescribing physician or health care professional
- recommend that the lay operator be trained in cardiopulmonary resuscitation

In the check-out instructions you should provide:
- A step-by-step procedure for checking proper functioning of all controls, indicators, and alarms
- A troubleshooting guide for use when there are indications of a monitor malfunction during checkout and/or operation
- Clear, simple diagrams and illustrations of the fully assembled and ready to operate monitor

In the operating instructions you should provide:
- warnings concerning the precautions necessary to avoid possible mis-operation or unsafe use of the monitor
- any pre-use cleaning or disinfecting procedures for the monitor and any accessories
- steps required to prepare the monitor for operation
- steps that must be taken by the operator to achieve the clinical purpose of the primary and secondary modalities
- proper connection of auxiliary devices
- description of appropriate warm-up procedures and intervals
- discussion of the positioning of sensors and electrodes, alternate electrode placement, preparation of electrodes and patient for electrode attachment, and identification of loose sensors and electrodes
- diagrams, illustrations or photos showing proper connection of the patient to the monitor and other equipment, if applicable, including alternate recommended electrode and sensor placement
- legible reproductions of all required labels and hazard warnings
- drawings or photos of all controls, alarms, and indicators provided with the monitor
- explanation of the use of the controls, alarms, and indicators
- list of error messages, if applicable, their meaning, and the corrective steps that can be taken by the operator
- procedures to follow in the event of a monitor alarm condition
- discussion of the proper use of remote alarm units, including recommended placement and the importance of the operator being able to access the patient within 15 seconds of alarm activation

Operator Maintenance Instructions

You should include in the operator maintenance instructions:

- recommendations for methods and materials for cleaning and disinfecting the monitor
- schedule of operator-initiated maintenance
- battery care and maintenance procedures, including instructions for recharging or replacement
- description of periodic visual safety inspections that should be performed by the operator

Patient Information

You should describe in the patient information:

- clinical circumstances which might require sensor adjustment or checking for proper operation
- circumstances related to the use of the monitor that could result in allergic, chemical, or thermal injury reactions
- instructions for preventing injury reactions, e.g., periodically repositioning electrodes

Operating Environment Information

In the operating environment information, you should discuss known or recognizable conditions of the environment that may affect the safe and effective use or operation of the monitor. FDA recommends including the following points.

- facility information, including a description of what should be expected if electricity to the monitor is lost
- effects of lint, dust, sun, light, heat, or humidity
- effects and possible sources of electromagnetic (conducted and radiated) interference
- effects and causes of electrostatic discharge
- list of other devices that pose potential electrical problems
- description of conditions of the sensors and electrodes, such as loosened electrodes, that can cause environmental effects to be more pronounced
- steps that can be taken by the operator to identify and resolve environmental interference

Service information

In the service information you should include the frequency of any calibration, repair, and periodic service or inspection, and a list of facilities and their locations, that provide service.

Healthcare Practitioner Operator Information

You should provide a healthcare practitioner operator instruction manual with each monitor. The manual should contain all of the information specified Home Use Operator Information in detail relevant to the healthcare practitioner, but need not be written at the seventh grade reading level. In addition, the manual should also contain:

- A description of equipment required for monitor use and mechanical and/or electrical specifications for electrodes, sensors, leads, cables, tubing, batteries, and accessories.

- Step-by-step procedures to prepare the monitor for initial and subsequent use. If a manual sensitivity control is provided, instructions as to when to use manual sensitivity and how to adjust the control for optimal breath detection.

- Step-by-step procedures recommended for determining whether the monitor is susceptible to the levels of electromagnetic interference occurring at the use location, a recommendation to repeat the testing periodically, and recommended action to take if the monitor fails the test. The preferred testing procedure for impedance/ECG monitors is as follows:

    (1) Set the monitor apnea duration to 20 seconds.
    (2) Connect the monitor to a patient simulator with all cables in extended rather than coiled configuration.
    (3) Set the simulator to output respiration and heart beats at rates and amplitudes that are within the normal range for humans less than 3 years of age.
    (4) Determine that the monitor detects respiration and heartbeats, at the rates to which the simulator is set.
    (5) Place the simulator in the apnea mode for 2 minutes.
    (6) Determine that the monitor continues to alarm for apnea at full volume beginning at 20 seconds. Alarming at reduced volume, false heart rate alarms, or self-silencing of the apnea alarm prior to the end of the simulated apnea constitute failure of this test.

- Precautions and a schedule of maintenance and calibrations necessary.

- Equipment specifications, including signal processing functions, algorithms, and averaging times for monitor functions that are applicable to the operation and use of the device.

- A statement as to whether or not pacemaker pulse rejection and defibrillator protection are included.

- A discussion of the importance of evaluating the anticipated response to apnea of candidate secondary monitoring parameters in relation to the conditon and needs of the patient, how this information should be used in selecting an appropriate secondary monitoring modality and in setting the secondary parameter alarm limits, and the importance of reevaluating the appropriateness of the secondary monitoring parameter and its alarm limit settings as conditions change (e.g., as the patient ages).

You should include he results of the clinical performance evaluations in the healthcare practitioner operation manual. The results should summarize the clinical performance evaluation procedures and protocols, the scoring criteria used during the evaluation, the analyses used, and the test results.

You should provide the date of issuance and the date of any revision of the health care practitioner operator instruction manual.

Label Specifications

Labels should be clearly legible at a distance of 1 meter in a range of illumination from 100 lux to 1,500 lux by an individual with a visual acuity of 1 (corrected if necessary). Permanently affix or inscribe labels on the exterior of the finished device. Labels should be resistant to removal or blurring from disinfectants and other normal use of the device.

You should label the controls, connectors, switches, and indicators identifying their functions.

Warning Labels

You should provide a permanent warning labels that read:

"Do not connect to an electrical outlet controlled by a wall switch." on monitors intended for use in the home that either operate from the AC power line or recharge batteries from the AC power line.

"NOT FOR HOME USE." on monitors intended for hospital use only.

"Inflate with room air only -- do NOT inflate from an oxygen supply." on any air mattress intended for use as part of an infant/child apnea monitor.

Servicing

FDA recommends that manufacturers of monitors provide instructions for service adjustment and service procedures to servicing dealers and distributors.

Glossary

(a) Apnea means cessation of respiratory air flow. The respiratory pause may be central or diaphragmatic (i.e., no respiratory effort), obstructive (usually due to upper airway blockage), or mixed (combination of central and obstructive).

(b) Artifact means a signal which may be misinterpreted by the monitor; the three most commonly recognized types of artifacts are cardiogenic, electromagnetic, and motion, as defined in paragraphs (c), (f), and (n) of this section.

(c) Cardiogenic artifact means an artifact produced by the electrical and/or mechanical activity of the heart.

(d) Component means any material, substance, piece, part, or assembly used during device manufacture that is intended to be included in the finished device.

(e) Damage means deformation, loosening, breakage, corrosion, change of fit of any component or part, or any other physical condition resulting in nonconformance of the monitor to the requirements of this guidance.

(f) Electromagnetic artifact means an artifact produced by extraneous electromagnetic energy.

(g) Finished device means any device or accessory to any device that is suitable for use or capable of functioning whether or not it is packaged, labeled, or sterilized.

(h) Health care practitioner means a doctor, nurse, therapist, or other health care provider who is licensed by the State or locality in which he/she practices or is credentialed by a nationally recognized agency.

(i) Infant/child apnea monitor means a complete system intended to alarm upon apnea and its pathophysiological consequences that is used on humans less than 3 years of age. The infant/child apnea monitor includes all items required for the intended operation of the device, such as: Sensors; electrodes; leads; cables; tubing; signal processing systems; alarm systems; power supplies; accessories supplied, recommended, or specified by the manufacturer of the monitor; accessories supplied, recommended, or specified for use with the monitor by the manufacturer of the accessory; and complete monitoring systems when the apnea function is supplied as a module intended for use on humans less than 3 years of age. The terms "device" and "monitor," when used in this guidance, also mean infant/child apnea monitor.

(j) Inspection means any examination, visual or auditory, performed without the use of special laboratory instruments or procedures and/or verification of manufacturing and test records.

(k) Intended means the same as "intended use(s) as specified by the manufacturer."

(l) Manufacturer means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.

(m) Monitor means an infant/child apnea monitor.

(n) Motion artifact means an artifact produced by movement of the patient.

(o) Operator means the individual who applies the infant/child apnea monitor to the patient, or who monitors the patient and the functioning of the device. The term "operator"

includes individuals, such as parents, nurses, therapists, care givers, etc., but does not include business entities, such as hospitals, corporations, partnerships, etc.

(p) Operator maintenance means performance by the operator or health care practitioner of those adjustments or procedures specified in the operator or health care practitioner information provided by the manufacturer for the purpose of assuring the continued safe and effective performance of the monitor.

(q) Patient means the individual being monitored by the infant/child apnea monitor.

(r) Primary monitoring modality means a method for detecting apnea.

(s) Reliably means dependably performing the intended function as indicated in the labeling.

(t) Secondary monitoring modality means a method that measures a physiological parameter that responds to the pathophysiological consequences of apnea, such as bradycardia, hypoxemia, or hypercarbia (hypercapnia).

(u) Service means performance of the procedures or adjustments described in the manufacturer's service instructions that may affect any aspect of the performance of the infant/child apnea monitor to which this guidance applies.

(v) Status indicator means a device subsystem that shows, in a timely manner, either the status or condition of a physiological parameter of the patient or a particular characteristic of the device.